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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
WANG, CHANG YU	
ART UNIT	**PAPER NUMBER**
1649	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/568,729	CASHMAN ET AL.	
	Examiner	Art Unit	
	Chang-Yu Wang	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *3/23/09*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27 and 29-51* is/are pending in the application.

4a) Of the above claim(s) *3-8, 18, 19, 23-27, 31-38, 40,42-46 and 50* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-2, 9-17, 20-22, 29-30, 39, 41, 47-49 and 51* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

RESPONSE TO AMENDMENT

Status of Application/Amendments/claims

1. Applicant's amendment filed 3/23/09 is acknowledged. Claim 28 is cancelled. Claims 1 and 17 are amended. Claims 1-27 and 29-51 are pending. Claims 31-38, and 42-46 are withdrawn with traverse (the response filed 8/7/06) from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim. In addition, claims 3-8, 18, 19, 23-27, 40 and 50 are also withdrawn from further consideration because of non-elected species.

2. Claims 1-2, 9-17, 20-22, 29-30, 39, 41, 47-49 and 51 are under examination with respect to prion, BSE, peroxynitrite and antibody in this office action.

3. On p. 11 of the response, Applicant argues that the restriction based on Kim is erroneous. In response, in contrast, based on MPEP 1893.03 (d), the examiner asserts that the requirement for the restriction is proper and has been made FINAL for the reasons made of record in the previous office action. Kim teaches a method detecting whether α-synuclein is in a wild-type or non-wild-type confirmation in the presence of Copper and H2O2, which meets the limitation that the blocking agent blocks accessible target epitopes in the wildtype conformation and the target epitope is inaccessible and cannot react with the blocking agent in a non-wildtype conformation as recited in instant claim 1 (see p. 544, abstract; p.545 materials and methods, Kim et al. Free Rad. Biol. Med. 2002. 32:544-550).

Based on MPEP 818.03 & 821.01-04, Applicant can take an appropriate action to petition the director to review the restriction requirement.

"after a final requirement for restriction, the applicant, in addition to making any reply due on the remainder of the action, may petition the Director to review the requirement."

4. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response.

5. Applicant's arguments filed on 3/23/09 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

Specification

6. The objection to the specification is withdrawn in response to Applicant's amendment to the specification and to the title.

Claim Rejections/Objections Withdrawn

7. The objection to claims 1, 3-8, 17, 18, 19, 23-27, 31-38, 40, 42-46 and 50 is withdrawn in response to Applicant's amendment to the claims.

The rejection of claims 1-2, 9-17, 20-22, 29-30, 39, 41, 47-49 and 51 under 35 U.S.C. 112, second paragraph, as being indefinite is withdrawn in response to Applicant's amendment to the claims and arguments.

Claim Rejections/Objections Maintained

In view of the amendment filed on 3/23/09, the following rejections are maintained.

Claim Objections

8. Claim 30 is objected because the status of the claim is incorrect. Applicant can cancel the claim but cannot withdraw the claim from consideration.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-2, 9-17, 20-22, 29-30, 39, 41, 47-49 and 51 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while enabling for detecting more epitopes recognized by antibodies 6H4 and 3F4 in prion protein PrP or a mutant PrP^{Sc} in brain homogenate treated with acid and peroxynitrite in the presence of guanidine then mock treated brain homogenate by immunoprecipitation using antibodies 6H4 and 3F4, does not reasonably provide enablement for the claimed method of detecting whether a structurally and functionally undefined candidate polypeptide with a unknown target epitope is in a wild-type or non-wild-type conformation by using an unknwon blocking agent to block a unknown accessible epitope in the polypeptide, modifying and determining whether the modified mutant is in a wild-type or non-wild-type conformation as broadly claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The rejection is maintained for the reasons made of record.

On p. 17-20 of the response, Applicant argues that instant claims are enabled because the specification shows a model prion made by acid treating wildtype PrP (resembles PrPSc), incubated with a blocking agent, peroxynitrite and subjected to immunoblotting using two detect agents 3F4 and 6H4 antibodies. Applicant argues that the specification provides several examples, defined epitopes, and different blocking agents. Applicant's arguments have been fully considered but they are not persuasive.

In contrast, the instant specification fails to provide sufficient guidance as to enable a skilled artisan to practice the full scope of the claimed invention because the instant specification fails to teach how to make and use all of the structurally and functionally undefined targets epitopes, candidate polypeptides, blocking agents and detection agents in the claimed method.

Based on the specification and prior art, Applicant is enabled for a method of detecting prion protein PrP or PrP^{Sc} in brain homogenate using antibodies 3F4 and 6H4. In addition, Applicant is enabled for a method of detecting more epitopes recognized by antibodies 3F4 and 6H4 in acid and peroxynitrite treated brain homogenate in the presence of guanidine as compared to mock-treated brain homogenate. However, the instant claims are not limited to the methods as set forth above. As previously made of record, independent claims 1, 39 and 49 encompass the detection of structurally and functionally undefined polypeptides, structurally and functionally undefined target epitopes, inaccessible and accessible target epitopes, and also encompass the use of structurally and functionally undefined blocking agents and detection agents.

As previously made of record, the claimed method is directed to a method of determining whether a protein is in a wildtype or non-wildtype confirmation. However, the claimed method itself encompasses a step of modifying polypeptide, which would change the wildtype conformation of a protein to a non-wildtype conformation since the step of modification recited in the claims is not limited to a specific method. Neither the specification nor the prior art teaches that any modification step can preserve a polypeptide in its wildtype confirmation. Thus, it is unpredictable whether all of modification methods would preserve the candidate polypeptide in its wildtype confirmation and can be used in the claimed method.

In addition, independent claims fail to limit what the claimed candidate polypeptide is, what the target epitope, accessible and inaccessible epitopes are and what the blocking and detection agents are. Although the specification teaches prion PrP treated with acid and peroxynitrite in the presence of guanidine can be detected more epitopes recognized by antibodies 3F4 and 6H4, the claims fail to limit what blocking and detection agents are and thus can be use in the claimed method. The specification fails to teach what other detection agent or method is except immunoprecitation of PrP with antibodies 3F4 and 6H4. The specification fails to teach what other candidate polypeptide, epitopes, blocking agents and detection agents can be used in the claimed method. Thus, it is unpredictable whether all of the structurally and functionally undefined candidate polypeptides, epitopes, blocking agents and detection agents can be used in the claimed method.

The specification fails to teach the structurally and functionally relationship between the prion PrP and other unknown polypeptides. The specification also fails to teach the structurally and functionally relationship between the epitopes recognized by antibodies 3F4 and 6H4 and other unknown epitopes, and nor does the relationship between 3F4/6H4 antibodies and other detection agents. Further, the specification also fails to teach the structurally and functionally relationship between peroxynitrite and other blocking agents or between acid or other modification method or agents. Thus, a skilled artisan cannot contemplate what polypeptides, epitopes, blocking agents, or detection agents are and thereby can be used in the claimed method.

The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without such guidance, it is unpredictable what changes can be made and still maintain activity; and thus the experimentation left to those skilled in the art is extensive and undue. See Ex parte Forman, 230 USPQ 546 (Bd. Pat. App. & Int. 1986). Thus, the skilled artisan cannot readily make and use the claimed invention as currently claimed without further undue experimentation. Note that

"The 'predictability or lack thereof' in the art refers to the ability of one skilled in the art to extrapolate the disclosed or known results to the claimed invention. If one skilled in the art can readily anticipate the effect of a change within the subject matter to which the claimed invention pertains, then there is predictability in the art. On the other hand, if one skilled in the art cannot readily anticipate the effect of a change within the subject matter to which that claimed invention pertains, then there is lack of predictability in the art. Accordingly, what is known in the art provides evidence as to the question of predictability. In particular, the court in In re Marzocchi, 439 F.2d 220, 223-24, 169 USPQ 367, 369-70 (CCPA 1971)" See MPEP § 2164.03

Claim Rejections - 35 USC § 112

10. Claims 1-2, 9-17, 20-22, 29-30, 39, 41, 47-49 and 51 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The rejection is maintained for the reasons made of record.

On p. 21-22 of the response, Applicant argues that instant claims meet the written description requirement because the specification provides numerous examples and a number of candidate polypeptides, blocking agents, modifying steps and detection agents for the claimed method.

In contrast, the specification only describes detecting more epitopes recognized by antibodies 3F4 and 6H4 in acid and peroxynitrite treated brain homogenate in the presence of guanidine as compared to mock-treated brain homogenate. The specification fails to teach what other defined polypeptides can be detected by the claimed method in a specific manner; in particular, there is no specific structural and functional relationship between PrP and other proteins that can be detected by the claimed method. There is no information about any particular portion of the structure that must be conserved for the claimed genus of structurally and functionally undefined candidate polypeptide, the genus of structurally and functionally undefined target epitope, accessible target epitope and inaccessible target epitope, the genus of blocking agent and the genus of detection agent. Since the functional and structural relationship

between the claimed polypeptides and target epitopes with no defined structures and PrP is unknown, a skilled artisan cannot envision the functional correlations between the claimed genera and the claimed invention without specific information. Thus, the specification fails to reasonably demonstrate that Applicant is in possession of the claimed method to detect all of structurally and functionally undefined polypeptides or epitopes with undefined blocking agents.

Note that

A definition by function alone "does not suffice" to sufficiently describe a coding sequence "because it is only an indication of what the gene does, rather than what it is." *Eli Lilly*, 119 F.3 at 1568, 43 USPQ2d at 1406. See also *Fiers*, 984 F.2d at 1169-71, 25 USPQ2d at 1605-06 (discussing *Amgen Inc. v.Chugai Pharmaceutical Co.*, 927 F.2d 1200, 18 USPQ2d 1016 (Fed. Cir. 1991)). An adequate written description of a chemical invention also requires a precise definition, such as by structure, formula, chemical name, or physical properties, and not merely a wish or plan for obtaining the chemical invention claimed. See, e.g., *Univ. of Rochester v. G.D. Searle &Co.*, 358 F.3d 916, 927, 69 USPQ2d 1886, 1894-95 (Fed. Cir. 2004).

In contrast, the specification provides an invitation for others to discover a representative number of species, or to discover what constitutes any particular portion of the structure that must be conserved, with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics. Thus, Applicants were not reasonably in possession of the claimed method.

Double Patenting

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re

Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 49 stands objected to under 37 CFR 1.75 as being a substantial duplicate of claim 1.

On p. 23 of the response, Applicant argues that claim 39 does not comprise contacting the polypeptide with a blocking agent and has fewer steps. Applicant's arguments have been fully considered but they are not persuasive.

In contrast, the claim does recite the blocking agent and the same steps. Thus, the objection is maintained.

12. Claims 1, 2, 12, 15-17, 20-22, 29-30, 39, 41, 47-49 and 51 stand rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 18-22 of U.S. Patent No. 7041807.

On p.23 of the response, Applicant argues that claims 18-22 of the '807 patent are not directed to an assay having the format like instant claims because the claims of the ‘807 patent are directed to an antibody binding to one particular epitope of PrPSC (i.e. the YYR epitope) and do not include a step of using a blocking agent. Applicant's arguments have been fully considered but they are not persuasive.

In contrast, the claims of the '807 patent are directed to a method for detecting PrP^{Sc} in a biological sample using an antibody that is able to recognize PrP^{Sc} wherein

the antibody selectively binds to PrPSc. The '807 patent's method is a species that anticipates the generic claimed method because the claimed method is directed to a method of detecting all forms of polypeptides including PrP^{Sc} using all forms of detecting agents including antibodies against PrP^{Sc}. In addition, since the instant claims do not limit the blocking agent used in the claimed method, any agent including antibody binding to epitopes of the PrPSc used in the method of the '807 patent meets the limitation of blocking agent and thus anticipated the instant claims.

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-2, 9-17, 20-22, 29-30, 39, 41, 47-49 and 51 stand rejected under 35 U.S.C. 102 (b) as being anticipated by US2002/0123072 (Prusiner et al. published Sep 5, 2002). Claims 1-2, 9-17, 20-22, 29-30, 39, 41, 47-49 and 51 stand rejected under 35 U.S.C. 102 (e) as being anticipated by US6677125 (Prusiner et al. issued Jan 13, 2004, priority Oct 9, 1998). These rejections are based on the subject mater that is enabled within the claims. The rejections are maintained for the reasons made of record.

Claims 1-2, 9-17, 20-22, 29-30, 39, 41, 47-49 and 51 as amended are directed to a method of detecting whether a candidate polypeptide including a target epitope is in a wildtype or non-wildtype conformation comprising contacting the undefined candidate polypeptide with an unknown blocking agent to block accessible epitope, removing the unreated blocking agent, modifying the candidate polypeptide to an unknnown mutant containing an inaccessible target epitope that is converted to accessible epitope, and then determining whether the unknown mutant is in a wildtype or non-wildtype conformation by an unknown detection agent. Claim 2 is directed to prion PrP^{Sc}, claim 9 is directed to use of peroxynitrite, claims 15-17 are directed to use of antibodies against prion and claim 41 is directed to use of dissociation enhanced lanthanide fluoroimmunoassay and time-resolved fluorescence.

Applicant addresses the 102 rejections anticipated by the '072 publication and the '125 patent together, thus Applicant's arguments will be answered together based on the reference of the ‘072 publication.

On p. 24-25 of the response, Applicant argues that Prusiner teaches the use of 3F4 antibody as a probe for disease PrPSc and the 3F4 antibody binds PrPc but not PrPSc. Applicant argues that Prusiner's method relies on the carefully controlled digestion step because Prusiner’s method is directed to the results as the object of the treatment is to hydrolyze as much non-disease protein as possible while hydrolyzing as little disease protein as possible. Applicant argues that no general hydrolysis reaction is able to achieve selective results because both PrPSc and PrPc are vulnerable to hydrolysis. Applicant argues that the claimed method offers a simple solution that

addresses the above issues. Applicant further argues that the claimed method is distinct and not obvious over the Prusiner's method because the claimed method requires the step of contacting the polypeptide with a blocking agent, which is the step not performed by Prusiner. Applicant's arguments have been fully considered but they are not persuasive.

In contrast, as previously made of record, Prusiner does teach the claimed method because Prusiner teaches a method of detecting the presence of a disease related to conformation of a protein PrP^{Sc} (non wildtype conformation) and a non-disease related conformation of the protein PrP^{C} (wildtype conformation) in a sample using an antibody specific for PrP^{Sc} such as 3F4 or antibodies in WO97/10505 (see p. 4, [0042]-p. 5, [0049]; p.6, [0089]-p.7, [0097] ; p. 7, [0098]-p.8, [0103]; p. 11-14, examples 1-4; p.15, claims 1-27, in particular), which meets the limitations as recited in instant claims 1-2, 9-17, 20-22, 29-30, 39, 41, 47-49 and 51.

In addition, in contrast to Applicant's arguments, Prusiner's assay does teach the step of contacting the polypeptide with a blocking agent that blocks accessible target epitope as recited in instant claims 1, 39 and 49. Prusiner teaches pretreatment of samples with antibodies binding to the non-disease conformation of the protein and remove the non-disease protein or pretreatment of samples with acids or alkaline or temperature or chemicals to destroy proteins that are not related to the assayed proteins (see p. 7, [0099], in particular), which meets the limitation as recited in independent claims 1, 39 and 49 and dependent claims 9-14 (including non-elected species in claim 9). Prusiner teaches detection of native PrP^{C} or denatured form of

PrP^{Sc} with an antibody against PrP using immunoprecipitation or ELISA or time-resolved dissociation-enhanced fluorescence (as in claim 41) (see p. 3, [0022]; p. 8, [0106]-p.9,[0116], in particular). Prusiner teaches detection more PrP^{sc} in denature form of PrP (i.e. non-wildtpe coformation) than in native form with selected antibodies such as 3F4 (see p.9, [0110]-[[0116], in particular) and also teaches detection of non-wildtype conformation of PrP as an indicator of prion disease as recited in instant claims 2, 20-22 (see p. 8, [0107]-p.9, [0109], in particular).

Prusiner also teaches that samples including brain or other biological samples are pre-treated and treated with acid, chemical or chaotropic salts, denaturing detergents, guanidine hydrochloride or proteinase to denature or unfold proteins as recited in instant claims 1-2, 9-17, 20-22, 29-30, 39, 41, 47-49 and 51 (see col.12-14, in particular).

Thus, the teachings of Prusiner anticipate claims 1-2, 9-17, 20-22, 29-30, 39, 41, 47-49 and 51.

Furthermore, note that a prior art of an issued US patent (the '125 patent) is a reference containing an "enabling disclosure" that the public was in possession of the claimed invention before the date of invention. In *In re Donhue*, the court held that

"Such possession is effected if one of ordinary skill in the art could have combined the publication's description of the invention with his [or her] own knowledge to make the claimed invention." *In re Donohue*, 766 F.2d 531, 226 USPQ 619 (Fed. Cir. 1985). See MPEP 2121.01.

Regardless of whether the carefully controlled digestion step in the Prusiner's method would be difficult to achieve perfect results, the Pruisner's method teaches all of the

steps used in the claimed method and is enabled to detect and determine a wildtype or a non-wildtype conformation of PrP. Thus, Prusiner anticipates the instant claims.

14. Claims 1-2, 9-17, 20-22, 29-30, 39, 41, 47-49 and 51 stand rejected under 35 U.S.C. 102(e) as being anticipated by US7041807 (Cashman et al., issued May 9, 2006, priority Jun 23, 1999). The rejection is maintained for the reasons made of record.

On p. 26 of the response, Applicant argues that Cashman does not teach the claimed method because Cashman teaches an antibody binding to one particular epitope of PrPSC (i.e. the YYR epitope) and do not include a step of using a blocking agent. Applicant's arguments have been fully considered but they are not persuasive.

In contrast, Cashman teaches a method for detecting PrP^{Sc} in a biological sample using an antibody that is able to recognize PrP^{Sc} wherein the antibody selectively binds to PrPSc as set forth in section of ODP. The Cashman's method is a species that anticipates the generic claimed method because the claimed method is directed to a method of detecting all forms of polypeptides including PrP^{Sc} using all forms of detecting agents including antibodies against PrP^{Sc} (see col. 11-14; col. 18-19; col. 25-28, in particular). In addition, since the instant claims do not limit the blocking agent used in the claimed method, any agent including antibody binding to epitopes of the PrPSc used in the Cashiman's method meets the limitation of blocking agent and thus anticipated the instant claims.

Conclusion

15. NO CLAIM IS ALLOWED.

16. This application contains claims 3-8, 18, 19, 23-27, 31-38, 40,42-46 and 50 drawn to an invention nonelected with traverse in the reply filed on August 7, 2006. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

17. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

18. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Papers relating to this application may be submitted to Technology Center 1600, Group 1649 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chang-Yu Wang whose telephone number is (571) 272-4521. The examiner can normally be reached on Monday-Thursday from 8:30 AM to 6:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker, can be reached at (571) 272-0911.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/CYW/
Chang-Yu Wang, Ph.D.
May 28, 2009

/Christine J Saoud/
Primary Examiner, Art Unit 1647